

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/553,552 04/20/00 LANGER

R 0492611-0326

EXAMINER

HM22/0619

C. HUNTER BAKER, M.D., PH.D.
CHOATE HALL & STEWART
EXCHANGE PLACE 53 STATE STREET
BOSTON MA 02109-2891

NGUYEN, D

ART UNIT

PAPER NUMBER

1633

DATE MAILED:

06/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/553,552

Applicant(s)

LANGER ET AL.

Examiner

Dave Nguyen

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claims 1-45 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Claims 13, 34, 38, 41 and 43 are generic to a plurality of disclosed patentably distinct species comprising:

- Ortho-ester;
- hydrazone; and
- and cys-acetonyl.

Should the species of ortho-ester be elected, the claims are generic to the species of the Markush group as set forth in claim 14, for example.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species as listed above and cited in the claims, even though this requirement is traversed.

Should the species of ortho-ester be elected, Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species as set forth in claim 14, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Claims 15 and 20 are also generic to a plurality of disclosed patentably distinct species comprising:

Mixed polymers; linear co-polymers, branched co-polymers and dendrimer branched co-polymers.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species of the

specific type of polymers as listed above, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Claim 16 is also generic to a plurality of disclosed patentably distinct species comprising:

The target agents as set forth in the Markush group of claim 16.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species of the specifically named targeting agent as listed in the Markush group, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Claims 17, 35, 38, 39 and 43 are also generic to a plurality of disclosed patentably distinct species comprising:

The therapeutic compounds as set forth in the Markush group of claim 35 including antisense agents, RNA and ribozymes; and

Any nucleic acid other than antisense agents, RNA and ribozymes.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species of the specifically named compound as listed in the Markush group, or to elect the above nucleic acid even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Claim 45 is also generic to a plurality of disclosed patentably distinct species comprising:

The known endosomal lysing component as set forth in the Markush group of claim 45.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species of the specifically named lysing component as listed in the Markush group, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these restricted species do not have any common structure, it would be unduly burdensome for the examiner to search and examine all of the species as encompassed by the breadth of the claims, and thus, restriction for examination purposes as indicated is proper..

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Any inquiry concerning this communication or earlier communications regarding the formalities should be directed to Patent Analyst Kimberly Davis, whose telephone number is (703) 305-3015.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is (703) 305-2024.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Clark*, may be reached at (703) 305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is (703) 308-0196.

Serial Number: 09/553,552
Art Unit: 1633

5

Dave Nguyen
Patent Examiner
Art Unit: 1633

DN

DAVE T. NGUYEN
PRIMARY EXAMINER